NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Performance Standard for *Vibrio vulnificus*; Request for Comments; 64 *Federal Register* 3300; January 21, 1999

Dear Sir or Madame:

NFPA is the voice of the $430 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three laboratory centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members, who produce processed and packaged foods, drinks and juices.

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General Comments

NFPA SUPPORTS THE DEVELOPMENT AND USE OF NEW TECHNOLOGIES TO ENHANCE FOOD SAFETY

NFPA encourages the development of processes and technologies that will reduce consumer risk from exposure to pathogens in raw food products, including *Vibrio vulnificus* from oysters or other molluscan shellfish. To the extent that any technology such as the AmeriPure process noted in FDA's request for comments can provide effective risk reduction while retaining the attributes of the raw product that some consumers seem to prize, its use should be permitted and even encouraged.

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STEPS SHOULD BE TAKEN TO IMPROVE COMPLIANCE WITH FEDERAL AND STATE REGULATORY REQUIREMENTS

The long association of FDA and State regulators with industry through the Interstate Shellfish Sanitation Commission (ISSC) has been a positive force for enhancing the safety of raw shellfish. Their achievements should not be minimized. Illegal harvesting and shipping activities can result in the sale of harmful product whether or not FDA determines to set a performance standard for *Vibrio vulnificus* in oysters from certain waters. FDA should work with State officials to enhance compliance with existing requirements regarding harvesting and shipping procedures that will reduce the threat of foodborne illness from consumption of raw molluscan shellfish.

NFPA encourages continued effort by the ISSC to address concerns about *Vibrio vulnificus*, as well as a host of other issues regarding the safety of shellfish products. In this regard, NFPA recommends reexamination of practices that will address risk associated with consumption of raw molluscan shellfish harvested from waters previously linked to illness from *Vibrio vulnificus* during those months when the population of this marine organism is known to rise to high levels in the water.

Responses to Specific Questions Raised in the FDA Notice

1. Is the AmeriPure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

   NFPA is not conversant enough with the AmeriPure technology to comment on its advantages and disadvantages or costs and availability. However, NFPA would object to the endorsement by FDA of any particular technology that is available only through proprietary license from a single supplier. NFPA strongly encourages the voluntary utilization of any appropriate technology that can be applied to reduce risk of illness associated with *Vibrio vulnificus* from molluscan shellfish.

2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of *V. vulnificus* in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of *V. vulnificus* to non-detectable levels?

NFPA makes no comment at this time regarding specific technologies and their application. However, NFPA does take issue with the non-detectable performance standard. Our comment in this regard is included with our answer to question 4.

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

   NFPA makes no comment at this time.

4. Would a performance standard have to be as low as "non-detectable?" Do data exist that would permit the setting of a performance standard above "non-detectable?" If so, at what level? Should the fact that *V. vulnificus* is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

   The use of performance standards is consistent with the modern concept of implementing HACCP-type control systems that are designed to meet specific goals. Thus NFPA believes it is appropriate to consider the usefulness of setting a performance standard designed specifically to achieve a certain risk-based public health objective when other effective means of controlling a hazard are unavailable.

   However, NFPA has seen no indication that a scientific risk assessment has been done that would support the need for adoption of a "non-detectable" level of *V. vulnificus* from molluscan shellfish. Indeed, the fact that *V. vulnificus* can be isolated from shellfish at virtually any time during the year from oysters harvested from certain waters and that these oysters are subsequently consumed with no known adverse health consequences signals the need to consider a different performance criterion. While a "non-detection" criterion will undoubtedly protect public health, this criterion may be unnecessarily conservative. Overly conservative criteria will have the effect of removing from consideration alternative techniques that may provide adequate protection to consumers. Thus, NFPA strongly urges the Agency to consider all available information as it considers this or any other performance standard.

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

   NFPA believes that any performance criterion identified must be based on providing an adequate level of public health protection but be applied only to the extent necessary to protect human health. Such performance criteria must be based on objective and scientific data, and must be based to the extent possible on an assessment of the actual

risks involved. Thus, at this time it appears that performance criteria must be considered on a case-by-case basis rather than prescribed for all molluscan shellfish.

6. What would be the quantifiable and non-quantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on costs be if a standard of "non-detectable" were put in place for all pathogens or for all raw molluscan shellfish?

   NFPA makes no comments at this time.

7. What would be the quantifiable and non-quantifiable benefits of a performance standard? Who would enjoy the benefits?

   A performance criterion that achieves a reduction in the risk associated with consumption of this product would be a benefit to at-risk individuals if they were to consume oysters that were subjected to a process designed to achieve the performance criterion.

8. Another marine pathogen, *V. parahaemolyticus*, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from *V. parahaemolyticus* have occurred from oysters harvested outside of the Gulf of Mexico region. Should a performance standard apply only to *V. vulnificus* or should it apply to other *Vibrio* species that post-harvest treatment might be able to reduce to non-detectable levels?

   NFPA understands that FDA is beginning a risk assessment on this particular problem and that the time line for this risk assessment is relatively short. NFPA recommends that the effectiveness of performance standards and processing techniques in reducing public health risks be included in this assessment. The output of the risk assessment should provide guidance in determining the most appropriate risk management strategy. NFPA requests that the Agency consider the same approach for evaluating the risk and various risk mitigation strategies for *V. vulnificus* from raw molluscan shellfish. Such an exercise will allow the Agency and the public to make a more informed assessment of the appropriateness of any performance criteria in reducing the risk of illness from this public health issue.

CONCLUSION

NFPA encourages the development of processes and technologies that will provide a reduction in consumer risk resulting from exposure to pathogens in raw food products, including *V. vulnificus* from molluscan shellfish. NFPA believes it is appropriate to consider the usefulness of setting a performance standard designed specifically to achieve a certain risk-based public health objective when other effective means of controlling a hazard are unavailable. However, NFPA has seen no indication that a scientific risk assessment has been done that would support the need for adoption of a "non-detectable" level of *V. vulnificus* from molluscan shellfish. NFPA understands that FDA is beginning a risk assessment on the problem posed by *V. parahaemolyticus* from molluscan shellfish. NFPA recommends that the effectiveness of performance standards and processing techniques to address this potential hazard be included in this risk assessment. The output of the risk assessment should provide guidance in determining the most appropriate risk management strategy.

NFPA requests that the Agency consider the risk assessment approach for evaluating the risk and various risk mitigation strategies for *V. vulnificus* from raw molluscan shellfish as well. Such an exercise will allow the Agency and the public to make a more informed assessment of the appropriateness of any specific performance criterion in reducing the risk of illness from *V. vulnificus*.

NFPA appreciates the opportunity to comment on this issue.

Sincerely,

Dane Bernard
Vice President, Food Safety Programs

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